

APR 27 2012

510(K) Summary**Submitter**

CSM Implant
Cho Sung Am
B205 Techno-Building, Kyoungpook National Univ.
#573-13, Bokhyun-dong, Buk-Gu, Daegu, Korea
Phone: 82-53-952-8261
Fax: 82-53-954-8261

Official Correspondent

Kodent Inc.
April Lee
325 N. Puente St. Unit B
Brea, CA 92821
Email: kodentinc@gmail.com
Phone: 714-525-0114
Fax: 714-525-0116

Device Information

Trade Name: CSM Internal-R Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 12/28/2011

Device Description

The CSM Internal-R Implant System is intended for use in partial or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations. The CSM Internal-R Implant system contains two types of fixtures, straight and tapered type based on the shape of the fixture. This system is made from titanium (Ti-6Al-4V ELI) and the surface treatment is done with Resorbable hydroxyapatite Blast Medium.

Indication for Use

The CSM Internal -R Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is intended for delayed loading.

Predicate Devices & Comparison

The subject device is substantially equivalent to the following predicate device:

- SQ IT System manufactured by Neobiotech Co., Ltd. (K090527)
- Atlas Implant System manufactured by CowellMedi Co., Ltd. (K071148)

Testing and other comparisons have established that the subject of CSM Internal-R Implant System is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

Comparison Chart

		Subject Device	Predicate Device	Predicate Device
510(K) Number		N / A	K090527	K071148
Device Name		CSM Internal-R Implant System	SQ IT System	Atlas Implant System
Manufacturer		CSM Implant	Neobiotech Co., Ltd.	CowellMedi Co., Ltd.
Indications for Use		Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design		Internal Design with straight and tapered	Internal tapered design	Internal, external, submerged with straight and design
Implant Sterile		Yes	Yes	Yes
Sterilization Method		Gamma	Gamma	Gamma
Abutment and cover screw sterilization method		Non-sterile	Non-sterile	Non-sterile
Surface Treatment		RBM (Resorbable Blasting Media)	RBM (Resorbable Blasting Media)	RBM (Resorbable Blasting Media)
Implant Diameters		3.5 – 4.8 mm	3.5 – 6.0 mm	3.5 - 5.0mm
Implant Lengths		8 – 14 mm	8 – 15 mm	8-14mm
Abutment	Diameters	3.5 – 5.5mm	3.5 - 6.0mm	3.5 - 6.0mm
	Lengths	4.0 -8.0mm	4.0 - 8.5mm	4.0 - 8.5mm
Angulations (Angled Abutment)		15°, 25°	15°, 25°	15°, 25°
Attachments		Various abutments and components	Various abutments and components	Various abutments and components
Implant material		Ti-6Al-4V ELI ASTM-F136	Ti-6Al-4V ELI ASTM-F136	Ti-6Al-4V ELI ASTM-F136
Cover Screw Material		CP. Ti. Gr. 4 ASTM-F67	CP. Ti. Gr. 4 ASTM-F67	CP. Ti. Gr. 4 ASTM-F67
Product Code		DZE, NHA	DZE, NHA	DZE, NHA

Substantial equivalence chart summary

The CSM Internal-R Implant System has a substantially equivalent intended use as the identified predicates, SQ IT System (K090527) manufactured by Neobiotech Co., Ltd. and Atlas Implant system (K071148) by Cowellmedi Co., Ltd. These systems are made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. CSM Internal-R Implant System and predicate device are made from titanium (Ti-6Al-4V ELI) and the surface treatment is done with RBM.

These predicate devices and CSM Internal-R Implant System have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutment. The subject and predicate devices are similar in size, surface treatment, and both are sterilized via gamma irradiation. When compared with predicate devices, no new questions of safety or effectiveness have been raised for the CSM Internal-R Implant System.

Non-Clinical Test Data

All of the data consistent with the recommendations in the FDA guidance document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004, mechanical testing of the implants demonstrated that the CSM Internal-R Implant System possess mechanical strength at least equivalent to the predicate devices.

Among the information and data presented in this 510(k) submission to support the substantial equivalence of the CSM Internal-R Implant System to the specified predicate devices, fatigue testing demonstrated that there is substantial equivalence in the performance, safety and effectiveness between the CSM Internal-R Implant System and the referenced predicate devices. Fatigue testing also demonstrated that this system meets its predefined acceptance criteria and performs in accordance with its intended use.

Safety and Effectiveness

CSM Internal-R Implant System is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device. The CSM Internal-R Implant System, as designed and manufactured, is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the referenced predicate devices.

K120043

Conclusion

The CSM Internal-R Implant System, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. Device presents no adverse health effects or safety risks to patients when used as intended. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, CSM Internal-R Implant System and its predicate devices are believed to be substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

CSM Implant
C/O Ms. April Lee
Official Correspondent
Kodent Incorporated
325 N. Puente Street,
Unit B
Brea, California 92821

APR 27 2012

Re: K120043
Trade/Device Name: CSM Internal-R Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 20, 2012
Received: April 25, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

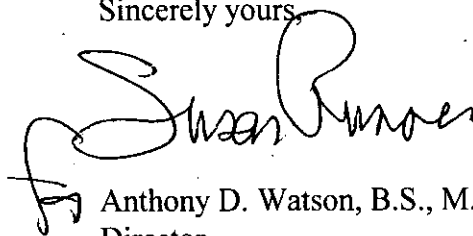
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", is written over a horizontal line.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K120043

Device Name: CSM Internal-R Implant System

The CSM Internal-R Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or over denture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is intended for delayed loading.

Prescription Use X
The-Counter

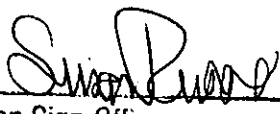
AND/OR

Over-

(Part 21 CFR 801 Subpart D)
21 CFR 801 Subpart C)

(Per

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Page 1 of 1

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120043